

the art... Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references.”

The Applicant has now amended the claims to more clearly define his invention. The claims now require that the corticosteroid is a mid- or high-potency corticosteroid and more preferably a high-potency corticosteroid. Most preferably, the high-potency corticosteroid is mometasone furoate or fluocinolone acetonide.

The Applicants have demonstrated that mid- or high-potency corticosteroids in combination with tazarotene provide more effective treatment of psoriasis than tazarotene, alone, or with a low-potency corticosteroid. (See lines 20-23 of page 9 of the present specification.) Tazarotene in combination with the mid- or high-potency corticosteroid produced significantly better results than treatment with tazarotene in combination with placebo in reducing plaque elevation, scaling, erythema and overall severity. This result is achieved surprisingly with fewer adverse events as pointed out at lines 26-29 of page 9 of the specification. “The most common adverse events resulting from the treatment were burning, pruritus and erythema; however there was a lower incidence of such adverse events in patients treated with tazarotene plus the medium- or high-potency corticosteroid.”

In Example 1, alclometasone dipropionate (mid-potency) and betametasone valerate (high-potency) in combination with tazarotene achieved consistently greater reductions than the combination of tazarotene and the low potency corticosteroid, hydrocortisone acetate, or tazarotene, alone and the high potency corticosteroid achieved plaque reductions within 2 weeks as compared to 4 weeks for other treatments. (See page 10, line 28 through page 11, line 5 of the present specification and Figure 1.) Also, see Figure 2, wherein the treatment success rate for the combination of tazarotene and mometasone furoate (high-potency) reached 75% at week 4 and remained at about such rate after 4 to 16 weeks of the initiation of the clinical trial. The success rate of the other treatments peaked at from 50 to 60 percent. (Note also that, demonstrating the unpredictability of the use of tazarotene in combination with corticosteroids of varying potency to treat psoriasis, the combination of tazarotene and the low potency corticosteroid achieved a greater success rate than the combination of tazarotene and the medium-potency corticosteroid.

Example 1 also demonstrates the surprising result that the combination treatment of tazarotene and a high potency corticosteroid achieves the greatest success rate of all of

the treatments with the fewest adverse events. See Table II on page 12 of the specification.

Finally, to show the results achieved in Example 1 is not due to the specific corticosteroids selected for combination with tazarotene. Example 2 utilizes chemically different low, medium and high-potency corticosteroids and achieves the same results. Nevertheless, the Examiner argues that "(t)he ordinary artisan would be motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized." It is believed that this argument is also incorrect, for as shown in Example 1, treatment success rate cannot be predicted based only on the use of a combination of compounds having a known utility for any given treatment. This is especially so in the context of the method of the present invention where the high potency corticosteroid gives the best results while achieving the lowest adverse events.

In view of the above, it is requested that the Examiner reconsider her rejection and find that the claims, as amended, are patentable over the cited art.

While no fee is thought to be due in connection with this communication, if Applicant is in error in this regard please use Deposit Account No, 01-0885 for the payment thereof.

Respectfully Submitted,



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